Form Approved. O.M.B. No. 0910-0444 Approval Expires 8/31/2003

U.S. Food and Drug Administration

NOTIFICATION FOR NEW USE OF A FOOD CONTACT SUBSTANCE

FOR NEW USES OF FOOD CONTACT SUBSTANCES

AGENCY USE ONLY

Date of Receipt

When completed send this form and notification to

NOTIFICATION CONTROL ASSISTANT
OFFICE OF PREMARKET APPROVAL
HFS-215
200 C STREET, SW
WASHINGTON, D.C. 20204

Enter the total number of pages in the Food Contact Notification

Date Effective (if effective)

FCN Number

GENERAL INSTRUCTIONS

FCN- ☐☐☐☐☐☐

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. You should make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the appropriate guidance for completion of notification for food contact substances.

Part I — GENERAL INFORMATION

Only one new use of an FCS may be the subject of a particular notification. A "new" use is one not otherwise authorized. If authorization is sought for use of multiple FCSs, separate notifications should be submitted for each new use. Any accompanying information for a notification may be provided to FDA in a Food Additive Master File and referenced in a notification. Any information referenced in a notification must be submitted to FDA prior to your notification. If you reference information from a third party that is located in other FDA files, provide a letter of authorization for such use, if necessary. For example, authorization is not necessary to reference publicly available information in FDA's files. If third party authorization is required, provide the name of the authorizing official for the third party and a mailing address.

Completion of this form alone may not constitute a complete notification for a new use of an FCS. A notifier must also submit all data and information that forms the basis of the notifier's safety determination for the use that is the subject of the notification and any data and information required by regulation. Five copies of your complete notification must be submitted, each with a ompleted and signed original or copy of this form.

Part II — CHEMISTRY INFORMATION

Summarize all pertinent information concerning the FCS that is the subject of the notification. This should include: chemical identity, manufacturing process, physical properties and specifications, conditions of use, intended technical effect, and stability data. In addition to the summary information provided, your notification should include all supporting information or data. Also, include sufficient data to enable FDA to determine the estimated daily intake resulting from the intended use of the substance. For information on recommendations on migration testing and presentation of the chemistry information see "Guidance for Industry: Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations".

Part III — SAFETY INFORMATION

Include a list of toxicology studies considered key to the safety decision, discuss the potential mutagenicity and carcinogenicity of the notified substance and its constituents, determine the ADI, as appropriate, and state the basis for the safety decision by the notifier. This information should be consistent with the discussion in the *Safety Narrative*, which is described in the "Guidance for Industry: Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations".

Part VI — LIST OF ATTACHMENTS

Attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. List these attachments, any test data or other data and any optional information included in the notification.

OPTIONAL INFORMATION

You may include any information that you want FDA to consider in evaluating this notification.

CONFIDENTIALITY OF INFORMATION

By submitting a notification under section 409(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)), a notifier waives any claim to confidentiality for information necessary to describe the food contact substance and the intended conditions of use that are the subject of the notification. If you are claiming any information in this notification to be confidential you should submit a redacted copy of the notification. FDA may disagree regarding the disclosability of information claimed confidential.

Part I — GENERAL INFORMATION

1a. Person Submitting Notice

Name of authorized official	Position

Company

Mailing address (number and street)

City, State, ZIP Code, Country

Telephone No.	Fax No.	E-Mail Address

☐ Please check here if E-Mail is your preferred method of communication.

b. Agent (if applicable)

Name of authorized official	Position

Company

Mailing address (number and street)

City, State, ZIP Code, Country

Telephone No.	Fax No.	E-Mail Address

☐ Please check here if E-Mail is your preferred method of communication.

2. If you had a prenotification communication (PNC) concerning this notification and FDA assigned a PNC Number to the communication, enter the number. →		Mark (X) if none → ☐
3. If you previously submitted an FCN for this substance that is not effective, enter the FCN number assigned by FDA. →		Mark (X) if none → ☐
4. List all effective notifications for the substance. → FDA maintains a list of effective notifications accessible through its internet site at "www.cfsan.fda.gov".		Mark (X) if none → ☐

Part II — INFORMATION ON IDENTITY, USE AND EXPOSURE

Section A - IDENTIFICATION OF THE FOOD CONTACT SUBSTANCE

1. Chemical Identity

a. Chemical Abstracts Service (CAS) name

b. Other chemical names (IUPAC, etc.)

c. Trade or common names

d. CAS Registry Number

e. Composition

Provide a description of the FCS, including chemical formula(e), structures and molecular weight(s). For substances that cannot be represented by a discrete chemical structure, such as polymers, provide a representative chemical structure(s).

For polymers, submit the M_W, M_n, and molecular weight distribution (including method) and, for copolymers, the ratio of monomer units in the copolymers.

☐ Mark (X) this box if you attach a continuation sheet.

f. Characterization

As appropriate, attach data to characterize the substance, including infrared (IR), ultraviolet (UV), nuclear magnetic resonance (NMR), or mass spectra, or other similar data for identification.

☐ Please check here if any of this information is attached and list the items below.

☐ Mark (X) this box if you attach a continuation sheet.

Section A - IDENTIFICATION - Continued

2. Manufacturing Process

a. List below all reagents, monomers, solvents, catalyst systems, purification aids, etc. used to manufacture the FCS, their chemical names, CAS Registry Numbers, impurities in each, the typical composition range of each in the total reaction mixture, and the maximum residual of each in the FCS intended to be marketed

Chemical Name (1)	CAS Reg. No. (2)	Major Impurities (3)	Typical Composition (4)	Maximum residual (5)
			%	%
			%	%
			%	%
			%	%
			%	%
			%	%
			%	%

b. Describe the manufacturing process, including times and temperatures, and include chemical equations for all synthetic steps and side reactions. Account for the fate of all substances listed in II.A.2.a.(1) that will not remain as residuals under II.A.2.a.(5). Describe any purification steps.

☐ Mark (X) this box if you attach a continuation sheet.

Section A - IDENTIFICATION - Continued

c. List impurities in the FCS including; the chemical name, CAS Registry Number, typical composition (percent weight) in the FCS intended for market, and the maximum residual in the FCS intended for market; for FCS that are polymers include typical and maximum residual monomer concentrations. Some of this data may be duplicated from Section II.A.2.a.

Chemical Name (1)	CAS Reg. No. (4)	Typical Composition (2)	Maximum residual (3)
		%	%
		%	%
		%	%
		%	%
		%	%
		%	%
		%	%

3. Physical Properties and Specifications

a. Provide physical/chemical specifications for the substance (e.g., maximum impurity levels, melting point) and relevant physical properties (e.g., solubility in food stimulants). Complete, to the extent possible, the "Physical and Chemical Properties Worksheet" included as an attachment to this form.

Properties	Values

☐ Mark (X) this box if you attach a continuation sheet.

b. For polymers, provide relevant information on density range, melt flow indexes, glass transition points, morphology, etc. Provide specification test results for at least three production batches of the substances. Attach methods for establishing compliance with specifications. Indicate the maximum percentage of low molecular weight species, not including residual monomers, reactants or solvents, below 500 daltons and 1000 daltons.

Polymer Properties	Values

☐ Mark (X) this box if you attach a continuation sheet.

Part II — INFORMATION ON IDENTITY, USE AND EXPOSURE — Continued

Section B - INTENDED USE

1. Describe the intended use of the FCS, including maximum use levels (or thickness) in food-contact materials, and types of food-contact articles in which it is expected to be used (e.g., films, coatings, molded articles). State whether single or repeated use is intended. Provide maximum temperatures and times of food contact, referring to classifications in 21 CFR 176.170(c) Table 2 when possible.

☐ Please check here if you attach a continuation sheet.

2. List types of food expected to contact the substance, with examples if known. Refer to classifications in 21 CFR 176.170(c) Table 1 when possible.

☐ Please check here if you attach a continuation sheet.

3. State the intended technical effect of the FCS and summarize data establishing the minimum amount of the substance required to achieve the intended technical effect. Attach data demonstrating that the FCS will achieve the intended technical effect.

☐ Please check here if you attach a continuation sheet.

Section C - STABILITY DATA

1. Will the FCS degrade, decompose, or undergo any other chemical change under the intended conditions of use? ☐ Yes ☐ No

2. Provide the basis for your conclusion. Attach any supporting data.

☐ Please check here if you attach a continuation sheet.

Part II — INFORMATION ON IDENTITY, USE AND EXPOSURE — Continued

Section C - STABILITY DATA - Continued

3. If the answer to C.1. above is "yes", list the degradation products for the FCS, and provide structures, CAS Reg. Nos. and molecular weights below.

☐ Please check here if you attach a continuation sheet.

Section D - ESTIMATED DAILY INTAKE (EDI)

1. Migration Testing and/or Calculations

Note: Summary information on migration testing and/or calculations should be provided here. A full report of all analytical testing, including detailed descriptions of methodology, raw data, and sample instrumental output (spectra, chromatograms, etc.) must be attached. In lieu of conducting migration testing, worst-case migration may be calculated by assuming 100% migration to food, or migration to food may be estimated through the use of different considerations. In such case, provide full details of calculations.

a. Describe test specimen(s), including full composition (e.g., comonomer composition of base polymer, identities and concentrations of adjuvants), dimensions (thickness and surface area), relevant base polymer properties (e.g., density, T_g, T_m, % crystallinity). For polymers, provide levels of residual monomer(s) in the test specimen(s). Indicate whether specimens were extracted by immersion or exposed on a single side.

b. Identify food simulants employed, and times and temperatures of extraction.

c. Summarize results of migration testing. Give average migration values (mg/in^2) for all analytes in each solvent at all time points. Provide sample calculations relating the instrumental output to values in mg/in2. For polymers, provide a measure of polymer migration and, if possible, characterize the individual low-molecular oligomer components. Also, provide a measure of monomer(s) migration.

d. Provide a summary of method validation results. Give average percent recovery for all analytes, food simulants, and spiking levels. Full details, including description of spiking procedure and calculations, must be included in attached report.

2. Estimated Daily Intake (EDI)

The incremental and cumulative EDI must be calculated by the notifier.

a. Calculate weighted-average migration (<M>) for each migrant by multiplying values measured in food simulants by appropriate food-type distribution (f_T) factors and summing over all for food types.

b. Calculate concentration of substance(s) in the diet by multiplying <M> value(s) by appropriate consumption factors (CF). Note: If CF values other than those assigned by FDA are used, information supporting derivation and use of such factors must be attached.

c. Calculate EDI, in milligrams per person per day, by multiplying concentration in the diet (expressed as mg per kg, or parts per million) by 3 kilograms/day average diet. Add the calculated EDI to the existing EDI for FCS, if applicable, to determine the cummulative EDI.

Part III — SAFETY INFORMATION

Section A - PIVOTAL TOXICOLOGY DATA

List the toxicology studies that the notifier believes justifies a conclusion that the intended use of an FCS is safe. Typically, the studies listed here should include the genetic toxicity studies and animal studies that are addressed in the *Safety Narrative* section of the toxicology data package, which is associated with this notification.

TYPE OF STUDY	SPECIES TESTED	SUBSTANCE TESTED	EFFECTS OBSERVED	NO-OBSERVED-EFFECT-LEVEL (NOEL)

Section B - MUTAGENICITY AND CARCINOGENIC POTENTIAL OF THE FCS AND ITS CONSTITUENTS

Discuss the scientific basis for your conclusions regarding the potential mutagenicity and carcinogenicity of the FCS and its constituents.

Section C - ADI DETERMINATION

Calculate an acceptable daily intake (ADI) by applying a suitable safety factor to the lowest suitable NOEL. If the FCS contains a carcinogenic constituent, estimate the risk associated with the estimated daily intake for such constituents.

Section D - NOTIFIER'S SAFETY DECISION

State the basis for the safety decision. If an ADI is available, compare it to the cumulative estimated daily intake (CEDI). In absence of an ADI, describe other considerations that are germane to the safety decision.

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) _____ .

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☐ Yes ☐ No

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes ☐ No

B - ENVIRONMENTAL ASSESSMENT

If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

Part V — CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

Signature of Authorized Official or Agent

Title

Date

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

To assist FDA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notice. Identify the property measured, the page of the notice on which the property appears, the value of the property, and the units in which the property is measured (as necessary). The measured properties should be for the FCS as proposed for use. Properties that are measured for mixtures or formulations should be so noted (%FCN substance in ___). You are not required to submit this worksheet; however, FDA strongly recommends that you complete the worksheet and submit it as a supplement to your test data. This worksheet is not a substitute for submission of test data.

Property (a)	Mark (X) if provided	Page number (b)	Value ©	Measured or Estimate (M or E)
Physical state of the substance	☐		☐ (s) ☐ (l) ☐ (g)	
Vapor pressure @ Temperature _____ °C	☐		Torr	
Density/relative density (specify temperature)	☐		g/cm3	
Solubility @ Temperature _____ °C Solvent _____	☐		g/L	
Solubility in water @ Temperature _____ °C	☐		g/L	
Melting Temperature	☐		°C	
Boiling/sublimation temperature @ _____ torr pressure	☐		°C	
Spectra	☐			
Dissociation constant	☐			
Particle size distribution	☐			
Octanol/water partition coefficient	☐			
Henry's Law constant	☐			
pH _____ @ concentration _____	☐			
Adsorption/coefficient	☐			
Other - Specify _____	☐			
Polymer specific (If a range is applicable, indicate so) % crystallinity of polymer	☐			
Degree of orientation	☐			
Thermal transitions of polymer (i.e., Tg, Tm)	☐			
Density of polymer (specify temperature)	☐			
_____	☐			

Part VI — LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form and test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, as appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment. Notifiers need not list other components of their notification not specifically referenced in this form.

Attachment name	Attachment page number(s)

☐ Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number.